Aesthetic outcome in patients after polymethyl-methacrylate (PMMA) cranioplasty - a questionnaire-based single-centre study

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Abstract: OBJECTIVES: Acquired skull deformities are common and most likely treated surgically by cranioplasty. Since data on patient aesthetic outcome after cranioplasty are rare in literature, we aimed to assess patient satisfaction after polymethyl-methacrylate (PMMA) cranioplasty in this study using a questionnaire. METHODS: A patient questionnaire was developed to evaluate the grade of satisfaction after surgery. After approval by the institutional ethical review board, we were allowed to send to all 115 patients, who received a cranioplasty from 2001 to 2008 at the University Hospital of Zurich, our questionnaire once to retrospectively analyze the patient response together with the patient hospital records. RESULTS: Out of 115 patients, 36 patients were lost to follow-up and our questionnaire was sent out once to 79 patients. Sixty-three of 79 patients replied to the questionnaire ($79 \cdot 7\%$) and 16 did not reply. Seventeen declined to participate in this study and out of the remaining 46 patients ($58 \cdot 2\%$, 18 women, mean age 54 years, range 20-83 years), who agreed to participate in this study, 22 ($47 \cdot 8\%$) judged their cranioplasty to be aesthetically 'excellent', 16 ($34 \cdot 8\%$) 'favorable' and 4 ($8 \cdot 7\%$) 'poor'. Another four patients ($8 \cdot 7\%$) were not satisfied, asking for a surgical revision. Patient age and gender was not related to the assessment of the aesthetic result. A higher satisfaction grade was found in patients with primary PMMA cranioplasty compared to PMMA cranioplasty implanted during a second surgery (Fisher's exact test, $P = 0 \cdot 031$). A dent was strongly associated with absence of satisfaction ($P<0 \cdot 01$, Fisher's exact test). CONCLUSION: Our questionnaire was suitable to assess patient satisfaction after cranioplasty. Localization of cranioplasty showed to be an important factor of aesthetic outcome, especially in the fronto-temporal region where a carefully planned reconstruction should be performed to guarantee an excellent grade of satisfaction after surgery.

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Aesthetic Outcome in Patients after Polymethyl-Methacrylate (PMMA) Cranioplasty - A Questionnaire Based Single Centre Study

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Keywords

Bone deformity, cranioplasty, polymethyl-methacrylate (PMMA), aesthetic outcome, questionnaire

Abstract

Objectives Acquired skull deformities are common and most likely treated surgically by cranioplasty. Since data on patient aesthetic outcome after cranioplasty are rare in literature, we aimed to assess patient satisfaction after polymethyl-methacrylate (PMMA) cranioplasty in this study using a questionnaire.

Methods A patient questionnaire was developed to evaluate the grade of satisfaction after surgery. After approval by the institutional ethical review board we were allowed to send to all 115 patients, who received a cranioplasty from 2001 to 2008 at the University Hospital of Zurich, our questionnaire once to retrospectively analyze the patient response together with the patient hospital records.

Results Out of 115 patients, 36 patients were lost to follow-up and our questionnaire was sent out once to 79 patients. 63 of 79 patients replied to the questionnaire (79.7%) and 16 did not reply. 17 declined to participate in this study and out of the remaining 46 patients (58.2%, 18 women, mean age 54y, range 20-83y), who agreed to participate in this study, 22 (47.8%) judged their cranioplasty to be aesthetically “excellent”, 16 (34.8%) “favorable” and 4 (8.7%) “poor”. Another 4 patients (8.7%) were not satisfied, asking for a surgical revision. Patient age and gender was not related to the assessment of the aesthetic result. A higher satisfaction grade was found in patients with primary PMMA cranioplasty compared to PMMA cranioplasty implanted during a second surgery (Fisher´s Exact Test $p=0.031$). A dent was strongly associated with absence of satisfaction ($p < 0.01$, Fisher’s Exact Test).

Conclusion Our questionnaire was suitable to assess patient satisfaction after cranioplasty. Localization of cranioplasty showed to be an important factor of aesthetic outcome, especially in the fronto-temporal region where a carefully planned reconstruction should be performed to guarantee an excellent grade of satisfaction after surgery.

Introduction

Acquired skull deformities often occur as a result of trauma or infection or may be caused by previous neurosurgical procedures using craniotomy (1-3). A variety of autogenous and alloplastic materials are available to surgically cover these skull defects. Besides others, polymethylmethacrylate (PMMA) is the most widely used material, due to its cost-efficiency compared to individualized preoperative computer-generated alloplastic implants (4-7). PMMA is an expedient biomaterial, stronger than the adjacent skull bone in compression, and the resultant shape is achieved by the surgeon during operation. However, a successful surgical coverage of a skull defect does not guarantee an aesthetic outcome satisfying to the patient. Especially, defects of the fronto-temporal skull region are more likely to cause aesthetic problems for patients, due to the highly visible location (8). The loss of insertion of the temporal muscle may additionally lead to functional problems, such as chewing difficulties.

To some extent, data on objective (radiographic findings) and subjective (patient satisfaction) aesthetic outcome after cranioplasty have been analyzed in literature, but questionnaires to quantify the patient subjective grade of satisfaction were not described yet (1, 9, 10). To identify factors influencing the grade of satisfaction, we developed a patient questionnaire to assess patient aesthetic outcome after PMMA cranioplasty.

Materials and Methods

After approval by the institutional ethical review board (No E-66/2009) we were allowed to send to all 115 patients, who received a cranioplasty from 2001 to 2008 at the University Hospital of Zurich, our questionnaire once to retrospectively analyze the patient response together with patient hospital records. Thirty-six patients were lost to follow-up due to change of address, change of name or unknown reasons before the questionnaire was sent out by

mail. All patients were treated with a standardized surgical protocol using PMMA Palacos® according to the company instruction (Heraeus Medical, Hanau, Germany). Briefly, the skull defect with its borders was operatively exposed in all patients followed by the size adjustment of the malleable PMMA cranioplasty. After hardening titanium miniplates and screws were placed on the solid PMMA cranioplasty followed by implantation. Patients with craniectomy received their cranioplasty after 3 months. Patients, who were still in neurorehabilitation during that time were transferred to our hospital for cranioplasty and retransferred to neurorehabilitation after surgery. No other implants than PMMA were used during that period of time at our department.

All patients provided written informed consent for this study, were older than 18 years and fluent in German. The following five questions in German were asked using a mailed survey:

1. Please estimate the size of your implant (small / medium / large)
2. Choose one of the following statements, which best describes your satisfaction with the aesthetic result of cranioplasty:
    a. I do not accept the aesthetic result after cranioplasty and would like to improve the appearance with another surgical intervention.
    b. I am not satisfied with the aesthetic result.
    c. I am satisfied with the aesthetic result.
    d. I am very satisfied with the aesthetic result and think that the cranioplasty does not impair my appearance at all.
3. If you are dissatisfied, please indicate the reason for your dissatisfaction: e.g. dents, bulges, scars, or bulging of bone edges
4. Did your grade of satisfaction change over time after cranioplasty?
5. Did you have any medical complications after cranioplasty?

Implant size was assessed objectively from radiology images and postoperative treatment from patient records. The slice of greatest cross-sectional area of the defect was chosen for size analysis: small, medium and large defects were defined as $\leq 50cm^2$, 50-$100cm^2$ and $\geq 100cm^2$, correspondingly. Information regarding infection parameter (11, 12) was obtained from the patient records.

Statistic analyses were performed using Spearman's rank correlation coefficient and the non-parametric Wilcoxon-Mann-Whitney test to correlate clinical variables with patient aesthetic outcome. The significance of the difference between proportions in a cross tabulation was assessed by Fisher's Exact test. All analyses were carried out with SPSS (PASW Statistics 19). P-values <0.05 were considered as statistically significant and p-values <0.1 were considered as a statistical trend.

Results

Patient general characteristics

The questionnaire was sent out to 79 patients (Table 1) and 63 (79.7%) replied. 16 patients did not reply (8 patients died and 8 patients did not answer for unknown reasons). 17 patients declined to participate and the remaining 46 patients (58.2%) agreed to participate in this study (18 women and 28 men, mean age 54 years, range 20 to 83 years).

The initial diagnosis before cranioplasty in the responder group (46 patients) was related to brain tumors in 21 patients (45.7%), to traumatic brain injuries in 14 patients (30.4%), to non-traumatic intracerebral bleedings in 6 patients (13%) and to other diseases in the remaining 5 patients (10.9%). Out of these 46 patients 6 patients (13%) had initially a bone flap infection before receiving a cranioplasty for the first time. Three different reasons for PMMA cranioplasty for our patient cohort were present: in 17 patients (Group I) autologous bone was used for cranioplasty during the initial surgery. However, postoperatively these patients became symptomatic with osteolysis / osteolysis with infection

and PMMA cranioplasty was implanted in a second surgery after autologous bone was removed. Group II contained patients (n=18) with PMMA implanted during primary surgery. Post-traumatic patients with unusable or absent autologous bone, which was removed during primary surgery, were summarized as Group III (n=11). PMMA was implanted in a second surgery and after detumescence of the injured brain in these patients.

Skull defects in the 46 responder patients were grouped based on their localization: 17/46 temporal (37%), 15/46 frontal (32.6%), 10/46 parietal (21.7%) and 4/46 occipital (8.7%) defects. The initial diagnosis of patients who declined or did not respond to this study (non-responder, n=33) included brain tumors in 19/33 patients (57.6%), traumatic brain injuries in 12/33 patients (36.4%) and any non-traumatic intracerebral bleedings. Initial diagnosis of 2/33 patients (6%) was related to other diseases. The initial bone flap infection rate of these patients was 21% (n=7).

Patient satisfaction grade

Of all 46 participating patients, 22 patients (47.8%) judged their cranioplasty to be aesthetically “excellent”, 16 patients (34.8%) judged “favorable”, 4 patients (8.7%) “poor” and 4 patients (8.7%) were not satisfied, asking for a revision. 11 out of the 24 patients, who did not judge “excellent”, described the source of their dissatisfaction as a disturbing dent since surgery. A dent was strongly associated with absence of satisfaction ($p < 0.01$, Fisher’s Exact Test).

Using crosstabulation statistics to compare the 3 different reasons for PMMA cranioplasty we could show that patients who received primary PMMA cranioplasty (Group II) rated their aesthetic result significantly more often with “excellent” than patients receiving their PMMA cranioplasty in a second surgery (Groups I and III) ($p=0.03$, Fisher’s exact test) (Figure 1).

As patients' assessment of the aesthetic result is the most important item in our questionnaire, we studied its correlation with the other items (Table 2). Neither did the gender of patients correlate with patients' assessment of the aesthetic postoperative result ($\rho = 0.10$, $p = 0.53$) nor did the patients' age ($\rho = 0.08$, $p = 0.58$). With regard to the localization of the cranioplasty, there was a trend in patients with posteriorly located cranioplasties to be more satisfied with the aesthetic postoperative result ($\rho = 0.28$, $p = 0.06$).

The occurrence of postoperative infection was indicated by 11 patients out of the 46 patients, who replied to the questionnaire. Seven of these patients had a diagnosed postoperative infection with regard to standardized infection criteria (Spearman's $\rho = -0.33$, $p = 0.03$). The patients with a postoperative infection tended to be more likely unsatisfied ($p=0.08$, Fisher's Exact test) compared to the rest of the patients. Five out of these 7 patients with diagnosed postoperative infection needed a revision surgery by means of explantation of the cranioplasty. Nevertheless, patients having a reoperation were just as satisfied as patients with no additional surgery after cranioplasty ($p=0.46$). None of these 7 patients with postoperative infection had a bone flap infection before their cranioplasty.

To put the patients' estimate of defect sizes into perspective, we compared the objective size of the cranioplasty with the patients' estimate. The subjective estimates and the objective findings showed large differences and there was no significant correlation between the two ($p=0.70$, Spearman's $\rho = 0.07$). Patients with smaller defects tended to be more satisfied than patients with larger defects (Spearman's $\rho = -0.29$, $p=0.06$).

Looking at the time course of satisfaction, 6 patients (13%) were more satisfied at the time answering the questionnaire than directly after cranioplasty. 29 patients (63%) were still as satisfied as after surgery. 3 patients (6%) were still as dissatisfied as after surgery and 6 patients (13%) indicate to be less satisfied at the time of the study than after surgery. All of the 6 less satisfied patients indicated in the questionnaire to have a dent in the area of cranioplasty and 2 of these patients mentioned to have additional asymmetry of the skull,

which might explain the reason for their dissatisfaction during follow-up. The initial diagnosis of these 6 patients before cranioplasty was traumatic brain injuries (n=2), non-traumatic intracerebral bleedings (n=2) and patients brain tumors (n=2). Two of the patients had a postoperative infection, none of them needed a revision surgery by means of explantation of the cranioplasty.

Discussion

In this study we analyzed for the first time the grade of postoperative aesthetic outcome in patients with PMMA cranioplasty using our questionnaire. The 79.7% overall response rate of the dispatched questionnaires is comparable to response rates from other clinical studies. For instance, a response rate in a range of 52% to 73.2% was previously described in other clinical studies (13-15). However, 17 patients in our study declined to participate. Both groups (responders and non-responders) consisted of a similar composition of patients with brain tumors and traumatic brain injuries as the most common initial diagnosis before PMMA cranioplasty. However, the initial bone flap infection rate of the non-responder group was twice as high in the responder group.

Comparing the 3 different reasons for PMMA cranioplasty in this patient cohort showed that patients receiving primary PMMA cranioplasty (Group II) were significantly more satisfied with their aesthetic result than patients receiving their PMMA cranioplasty in a second surgery (Group I, III) (Figure 1). These findings were expected, since multiple surgeries more likely have a negative effect on the patient satisfaction grade.

Patients with cranioplasties in the posterior region were more likely satisfied than patients with operations in the frontal or temporal region. In this region the defect is obviously more exposed due to the incomplete hair coverage. Atrophy of the temporal muscle seems to be an additional factor in our patient series, which is associated with aesthetic and functional problems after pterional craniotomy and reconstruction of the pterional region (16-17). In our

study, unsatisfied patients complained most likely about the dented aesthetic look or temporal wasting as previously described by Raza et al., which may lead to functional disturbances such as chewing problems (16).

Cranioplasty of the fronto-temporal region might therefore be considered to be rather planed individually after surgery by means of computer-assisted developed cranioplasties than free-hand cranioplasties, which are generated during surgery. This is supported by the findings of previous published studies using computer-assisted design/computer-assisted modeled (CAD/CAM) materials such as titanium, polyethylene, hydroxy-apatite, glass bioceramic, which already proved their efficacy(18-22). For instance, comparing CAD/CAM titanium implants for cranioplasty with other frequently used materials, Cabraja et al showed that 88% of the patients were satisfied with the cosmetic result of titanium implants (18).

Comparing the objective size of the cranioplasty with the patients' estimate, the subjective and objective findings showed large differences without any significant correlation between the two ($p=0.70$, Spearman's $\rho = 0.07$). These findings are confirmed by Dujovny et al. who suggest that psychological effects caused by bone deformities may evoke a need for cosmetic correction regardless of the size. Especially in defects located in the frontal region even small deformities, such as burr holes, were found to be distracting by the patient (23). However, taking the objective size of the defect into account, patients in our series tend to be more satisfied with smaller defects compared to patients with larger defects (Spearman's $\rho = -0.20$).

As to infection rate, our objective infection rate of 15.2% (7 out of 46 patients) is in the lower range compared to previous reported infection rates (range 16-34%) (24). Moreira-Gonzalez et al. showed that the material for the skull reconstruction seems to be correlated with the rate of infection and conclude that autologous bone graft and PMMA are still the materials of choice for calvarial reconstruction (25). Our patients were well informed about their postoperative infection, since there was a significant correlation between the patient

responses and objective criteria (p=0.02, Spearman's ρ = -0.33). Patients with a postoperative infection tended to be more likely unsatisfied (p=0.06) compared to the rest of the patients. There was a discrepancy that remained unclear to the authors in that four patients indicated to have experienced an infection, which, however, contradicted our patient records.

Patients received cranioplasty after trauma were less satisfied than patients received cranioplasty due to other reasons (ρ = -0.21). This might be caused by posttraumatic affective disorder, which may occur after brain injury or posttraumatic stress disorder (26-28).

Conclusions

In conclusion, our questionnaire is suitable to assess patient satisfaction after cranioplasty. Based on our results we conclude that 1) overall most of the patients were satisfied with their cranioplasty (38 out of 46 patients judged their cranioplasty to be aesthetically "excellent" or "favorable") with a low complication rate; 2) localization of the cranioplasty is an important factor of aesthetic outcome; 3) patients receiving primary PMMA cranioplasty were significantly more satisfied with their aesthetic result than patients receiving their PMMA cranioplasty in a second surgery. Based on these findings, we recommend planning the reconstruction of fronto-temporal cranioplasties carefully. To guarantee an excellent grade of functionality and aesthetics, computer-assisted methods should be considered for fronto-temporal cranioplasties. In any case, regardless of the chosen cranioplastic method, reconstruction in this aesthetically demanding region should be planned and performed with the utmost care.

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Figure Legend

Figure 1: Patient satisfaction depends on surgery type. In patient group I, PMMA cranioplasty was implanted in a second surgery after autologous bone was removed. In patient group II, PMMA cranioplasty was implanted during primary surgery. In patients with unusable or absent autologous bone (group III) PMMA was implanted after detumescence of the injured brain. Patient ratings of the aesthetic appearance of their implants was dichotomized to "excellent" (black bars) and "not excellent" (white bars). The proportion of patients who rated the aesthetic appearance of their implant as "excellent" was larger in group II than in groups I and III. The significance of the difference between the proportions was assessed in a cross-tabulation using Fisher's Exact test ($p = 0.03$).